FDA'S 1994 Priorities

As in the past, numerous factors outside the control of the Food and Drug Administration (FDA) will impact upon the Agency's resources and responsibilities during the decade to come. These factors include: (a) President Clinton's health care reform proposal; (b) President Clinton's childhood immunization initiative; (c) the explosion in biotechnology products; (d) the AIDS epidemic; (e) the health care needs of an aging population; and (f) an increased emphasis on international harmonization by the industries regulated by FDA.

In addition to these general factors, a number of specific issues will require increased FDA attention. These include: (1) reducing review times for new product applications; (2) pesticide residues in the foods we eat; (3) unapproved uses of FDA-regulated drugs and devices; (4) high levels of contamination in imported foods and seafood; and (5) inadequate regulation of dietary supplements.

Against this backdrop, FDA has established the following priorities for 1994:[1]

Product Safety

- Develop more accurate risk assessment models and analytical methods to guide regulatory decisions for all products.
- Implement pre-marketing and post-marketing safety reporting requirements; expand the MEDWatch program.
- Promote reporting of errors and accidents relating to blood safety; continue increased scrutiny of the blood industry.
- Implement mandatory seafood inspection program and establish new seafood rules; update food safety guidance for the states.
- Review regulations governing food biotechnology.
- Reform system to assure the safety of pesticides.
- Promulgate final rule concerning sulfiting agents in foods.

[1] The items on this list are drawn from FDA documents and recent speeches by FDA Commissioner David Kessler.

Product Approvals

- Reduce review times for new product applications, particularly those that treat life-threatening or disabling infirmities.
- Reduce the backlog of medical device applications; revoke investigational device exemption for intraocular lenses.
- Increase capabilities to assess applications for new biotechnology and gene therapy products.
- Improve the quality of clinical trials of drugs and devices to assure the availability of data on women and minorities.
- Implement the Mammography Quality Standards Act of 1992.
- Implement rules for donor screening and for testing of musculo-skeletal and other non-vascularized tissues.
- Revise the regulations governing review of new animal drug applications (NADAs); issue regulations for investigational new animal drugs (INADs).

Health Claims/Product Labeling

- Improve product labels and other information so that consumers and health professionals can make informed use of FDA-regulated products, including labeling for dietary supplements and disclosure of drugs used in food-producing animals.
- Review package inserts, use instructions, and precautionary information regarding childhood vaccines.
- Promulgate regulations on pediatric labeling.
- Accelerate the implementation of the FDA process to establish conditions under which over-the-counter drugs are considered generally recognized as safe and effective and not misbranded.
- Review regulations regarding dietary supplements, such as vitamins, minerals, amino acids, herbs and other similar nutritional substances.

Enforcement

- Conduct pre-approval inspections for all product licensing.
- Inspect all firms on FDA's establishment inventory at least once every two years, with extra emphasis on high risk companies.
- Increase scrutiny of the more than 4,000 imported items under FDA jurisdiction which enter the country each day; install new information systems and a new electronic interface between FDA, the U.S. Customs Service and the brokerage community.
- Increase agency capabilities to detect and take enforcement action against counterfeiting, fraudulent activities and tampering.
- Disqualify clinical investigators involved in fraud or other serious violations of the regulations.
- Increase the number of law enforcement cases investigated and prosecuted jointly by FDA and other federal and state agencies.
- Exercise improved control over off-label uses and their promotion.
- Impose penalties on drug products with labels based on false or fraudulent data or information.

Management

- Acquire state-of-the-art facilities and scientific equipment.
- Hire and train 1,400 new employees to work in the areas of medical devices, AIDS and generic drugs.
- Hire and train new medical reviewers as required by the Prescription Drug User Fee Act of 1992.
- Increase scientific and technical expertise to keep pace with accelerating research and development expenditures by regulated industries.
- Reduce the gap between private sector and public sector salaries that makes FDA recruiting difficult.